PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Shyam B. Karki et al.
Serial No.:	10/544,213 **Case No.:** 21346P
Filed:	August 2, 2005
For:	Formulations For Tyrosine Kinase Inhibitors

Art Unit 1609

Auth. Off.: N. Westerberg

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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MERCK & CO., INC.
By _____ Date 8/23/07

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

This paper is filed in response to the restriction requirement mailed August 17, 2007 and for which a response is due on September 17, 2007. Claims 1-26 are currently pending in the application and are subject to the following restriction under 35 U.S.C. 121 as follows:

Group I Claims 1-6, drawn to powdered formulations.

Group II Claims 7-12, drawn to granulated formulations.

Group III Claims 13-24, drawn suspension formulations and kit for preparing suspension formulations.

Group IV Claims 25 and 26, drawn to method of treating cancer.

Applicants elect the invention of Group I (Claims 1-6, drawn to powdered formulations).

Applicants respectfully assert that the Examiner fails to justify the restriction requirement because contrary to the Examiners' assertion, the present invention of Groups I-IV is related. The present invention is closely related in structure, i.e., the compound 3[5-(4-methanesulfonyl-piperazin-1-yl)-1H-indol-2-yl]-1H-quinolin-2-one (referred to here in as "2-one") is used to make the powder or granulation formulation as well as the kit. Also, the compound in used to treat cancer.

Additionally, 35 U.S.C. 121 specifies that if two or more independent and/or distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions. See MPEP 802.01. Independent generally means that there is no disclosed relationship between the two or more claimed inventions. "Distinct" means that the inventions, although related, are capable of separate use and patentably distinguishable. Furthermore, even though only one invention may be claimed in a single application, a reasonable number of species of the invention can be claimed if there is an allowable generic claim in the application, which is the case of the present application. Accordingly, there is no additional burden on the part of the Examiner to conduct the prior art search for examination of the present application in total.

In view of the fact that the present claims are all related to the same compound there would be no serious burden placed on the Examiner in conducting a search and examination of Groups I-IV in the same application. It is both possible and eminently sensible to search all of the claims in a single application, because any reasonably comprehensive search for information relevant to the compound involved in the invention as a powder or granule would inevitably require a search of and result in information relevant to both types. It would seem then, that to require the filing of a separate divisional application directed to Groups II, III and IV will result in the very same search regarding the "2-one" compound as a powder or granual formulation . It is submitted that this duplicate search would be quite inefficient to the operation of the Patent & Trademark Office. The more efficient process, given the well-defined core, would be to search all compounds at once using the sub-structure search capability available on commercial databases (e.g., Chemical Abstracts and Registry on STN). There is no undue burden.

Moreover, as a result of the recently enacted GATT legislation limiting the term of a patent to twenty years from its effective filing date, the delay in the examination of the non-elected claims will likely result in a the patent term for these claims being unnecessarily shortened. Therefore, because the only logical outcome of the present restriction requirement would be to delay the further examination of the non-elected claims, resulting inefficiencies and unnecessary expenditure by the Applicants, and because a single search can be performed for all groups claimed without any significant burden on the Patent Office, it is respectfully requested that the restriction be withdrawn.

In view of the foregoing, it is Applicants' position that the subject application has unity of invention and in any event a search of all the claims in a single application poses no undue burden. Accordingly the restriction requirement is improper.

In view of the above, the Examiner is respectfully requested to withdraw the restriction requirement.

Authorization is hereby given to charge any fees which may be due as a result of this petition to Deposit Account No. 13-2755.

Respectfully submitted,

By: _____

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Date: August 23, 2007